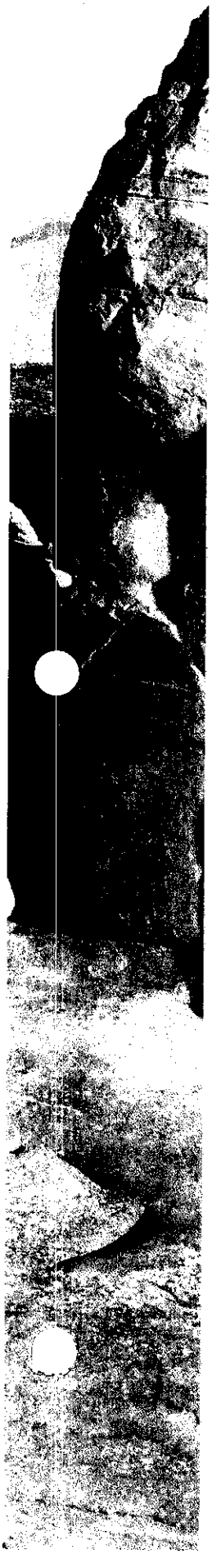
ULTRADENT PRODUCTS, INC.

K071055

Section II

MAY - 3 2007

510(k) SUMMARY



Submitter:

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095
Phone: (801) 552-5512
Fax: (801) 553-4609
E-mail: wrobert@ultradent.com
Robert Wang – Contact Person

Date Summary Prepared: March 13, 2007

DEVICE

Trade Name: ***Opal Prime & Opal Bond/***
Orthodontic Composite Bracket System
Common Name: Orthodontic Bracket Adhesive Primer & Paste
Classification Name: Adhesive, Bracket and Tooth Conditioner, Resin
Regulation Number: 21 CFR 872.3750

PREDICATE DEVICE

Orthodontic Composite Bracket System
Ultradent Products, Inc.

DESCRIPTION AND INTENDED USE:

The Orthodontic Composite Bracket System is a self-ligating orthodontic bracket uniquely formed in a one piece unit and includes an Adhesive Paste and Adhesive Primer. This system is a bondable device for fixed attached orthodontics.

COMPARISON WITH PREDICATE DEVICE

Opal Prime & Opal Bond is substantially equivalent in composition and intended use to the predicate device listed above. The modified *Opal Prime & Opal Bond* has the same Intended Use and has the same Fundamental Scientific Technology as the original ***Opal Prime & Opal Bond/ /Orthodontic Composite Bracket System*** currently manufactured by Ultradent Products Inc., please see Section VII for the entire comparison.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Robert Wang
Senior Regulatory Affairs Product Specialist
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

MAY - 3 2007

Re: K071055
Trade/Device Name: Opal Prime & Opal Bond Orthodontic Composite Bracket System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Codes: DYW and DYH
Dated: March 13, 2007
Received: April 16, 2007

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): ~~Unknown~~ K071055

Device Name: *Opal Prime & Opal Bond/Orthodontic Composite Bracket System*

Indications for use:

The Orthodontic Composite Bracket System is a self-ligating orthodontic bracket uniquely formed in a one piece unit and includes an Adhesive Paste and Adhesive Primer. This system is a bondable device for fixed attached orthodontics.

Prescription Use: ✓ AND/OR Over-The-Counter Use: _____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner
(Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...0(k) Number: K071055